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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,986	09/08/2000	Edwin L Madison	225/049	2665

7590                    03/26/2003

SUZANNE L. BIGGS  
PILLSBURY WINTHROP, LLP  
50 FREMONT STREET  
P.O.BOX 7880  
SAN FRANCISCO, CA 94105

[REDACTED] EXAMINER

WALICKA, MALGORZATA A

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1652

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/657,986	MADISON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 30 December 2002.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2 and 4-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 6 and 7 is/are allowed.
- 6) Claim(s) 1,2,4 and 5 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22.
- 4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: copies of the patent used in 35 USC section 102 rejection.

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Amendment under 37 CFR § 1.111, filed on Dec. 30, 2002 as paper 21, is acknowledged. Amendments to the claims and specification have been entered as requested. Claims 3 and 8-15 are canceled; claims 1-2, and 4-7 are the subject of this Office Action.

## OFFICE ACTION

### ***1. Restriction/election***

In their response Applicants request that because the elected species, the compound having structure No. 4 has been found allowable, the scope of search of the elected invention, Group I, current claims 1-2, and 4-7, should be increased and encompass all other structures claimed, i.e., structures Nos. 1-3, and 5-23. Thus, the compounds having structures identified as Nos. 1-3 and 5-23 are included into examination on merits.

### ***2. Objections***

The objection to Figure 1 is withdrawn. The examiner acknowledges the copies of Figures as filed.

Objection to claim 7 is withdrawn, because the amended claim 7 presents the structures of compounds toward which it is directed.

### **3. Rejections**

#### ***3.1. 35 USC, section 112, second paragraph***

Rejection of claims 1-2 and 4-5, for reciting the abbreviation MTSP1 without its expansion, is withdrawn, because the claims have been amended.

*Wilson* The term "selectively" in claim 4 is a relative term, which renders the claim indefinite. The term "selectively" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

### 3.2. 35 USC, section 112, first paragraph

#### 3.2.1. Rejection for lack of written description

Claim 2 and 5 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Neither the claims nor specification describe any inhibitor that has an IC<sub>50</sub> of 100 nM or less.

Rejection of claim 1-2 and 4-7 for lack of written description of the large and variable genus of chemical compounds that are inhibitors of serine proteases is withdrawn, because the amended claims recite specific protease inhibitors by identifying their chemical structures.

#### 3.3. Rejection for scope of enablement

Claims 1-2 and 4-5 were rejected under 35 U.S.C. 112, first paragraph, in the previous office Action paper No. 18, because the specification, while being enabling for

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a method of treating with the compound No. 4, does not reasonably provide enablement for treatment with any inhibitor of serine protease activity of matriptase or MTSP1, and because claims 2 and 5 are directed to the method of treatment with an inhibitor wherein the inhibitor's IC<sub>50</sub> is of 100 nM or less, whereas the specification is silent about an inhibitor having IC<sub>50</sub> that is of 100 nM or less.

This rejection is withdrawn because Applicants' arguments have been found persuasive.

#### 3.4. 35 USC section 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patents No. 5,492,895 issued to Vlasuk et al. on Feb. 20, 1996; 5,696,231 issued to Abelman et al. on Dec. 9, 1997; No. 5, 776, 027, issued to Abelman et al. on July 1998.

The claims are directed to compounds having structures identified as No.1, 2, 15 and 17. Structure No. 1 is disclosed in the US patent 5,696,231; see claim 1of the patent. Structure No. 2 is disclosed in the US Patents No. 5, 492, 895; see claim 1of the patent. Structure No. 15 is disclosed in the US Patent No. 5, 776, 027; see claim 22 of the patent. Structure No. 17 is disclosed in the US patent 5,696,231; see claim 22 of the patent.

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**4. Conclusion**

As indicated in the previous Office Action, paper No.18 the application contains allowable subject matter. Claims 6 and 7 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

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Patent Examiner

~~TECHNOLOGY CENTER 1600  
SUPERVISORY PATENT EXAMINER  
PONNATHAPUACHUTAMURTHY~~  
  
PONNATHAPUACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600